

Department of Health  
Notice of Rulemaking Hearing  
Tennessee Medical Laboratory Board  
Division of Health Related Boards

There will be a hearing before the Tennessee Medical Laboratory Board to consider the promulgation of amendments to rules and a new rule pursuant to T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-105, 68-29-113, 68-29-118, 68-29-119, and 68-29-126. The hearing will be conducted in the manner prescribed by the Uniform Administrative Procedures Act, Tennessee Code Annotated, Section 4-5-204 and will take place in the Tennessee Room of the Cordell Hull Building located at 425 Fifth Avenue North, Nashville, TN at 3:30 p.m. (CDT) on the 16th day of June, 2006.

Any individuals with disabilities who wish to participate in these proceedings (review these filings) should contact the Department of Health, Division of Health Related Boards to discuss any auxiliary aids or services needed to facilitate such participation or review. Such initial contact may be made no less than ten (10) days prior to the scheduled meeting date (the date such party intends to review such filings), to allow time for the Division to determine how it may reasonably provide such aid or service. Initial contact may be made with the ADA Coordinator at the Division of Health Related Boards, First Floor, Cordell Hull Building, 425 Fifth Avenue North, Nashville, TN 37247-1010, (615) 532-4397.

For a copy of the entire text of this notice of rulemaking hearing contact:

Jerry Kosten, Regulations Manager, Division of Health Related Boards, 425 Fifth Avenue North, First Floor, Cordell Hull Building, Nashville, TN 37247-1010, (615) 532-4397.

Substance of Proposed Rules

Amendments

Rule 1200-6-1-.06 Fees, is amended by deleting subparagraphs (1) (b) and (3) (b) in their entirety and renumbering the remaining subparagraphs accordingly.

Authority: T.C.A. §§ 4-5-202, 4-5-204, and 68-29-105.

Rule 1200-6-1-.12 Continuing Education, is amended by inserting the following language as new part (1) (a) 30. and renumbering the remaining parts accordingly, and is further amended by adding the following language as subparagraph (1) (d), and is further amended by deleting subparagraph (3) (b) in its entirety and substituting instead the following language, so that as amended, the new part (1) (a) 30. and the new subparagraphs (1) (d) and (3) (b) shall read:

(1) (d) Continuing education credit will be assigned on the following basis:

1. Any single session lasting not less than two and one-half (2½) clock hours will be assigned three (3) hours of continuing education credit.
2. Any single session lasting not less than one (1) clock hour and forty (40) clock minutes will be assigned two (2) hours of continuing education credit.
3. Any single session lasting not less than fifty (50) clock minutes will be assigned one (1) hour of continuing education credit.
4. The hours assigned shall be based on actual instruction or program time, excluding registration time and breaks, but including question and answer time.

(1) (a) 30. Southern Association of Clinical Microbiologists.

(3) (b) The individual must, within thirty (30) days of a request from the board, provide evidence of continuing education activities. Such evidence must be by submission of one (1) or more of the following:

1. Photocopies of certificates verifying the licensee's attendance at continuing education program(s). The certificate photocopies must include the following: continuing education program's provider, date, clock hours awarded (continuing education units must be converted to clock hours), program title, and licensee's name.
2. Photocopies of original letters on official stationery from the continuing education program's provider indicating, date, clock hours awarded (continuing education units must be converted to clock hours), program title, and licensee's name.
3. Photocopies of certificates or letters verifying successful completion of a written post experience examination to evaluate material retention upon completion of a multi-media and/or electronic course, as provided in paragraph (4). The certificate or letter photocopies must include the clock hours awarded (continuing education units must be converted to clock hours), program title, and licensee's name.
4. Preparing and teaching continuing education courses [subparagraph (1) (b)] – A letter from the education director, laboratory director, department head, dean of the institution, or officer of the approved organization attesting that the course was presented and including time spent in classroom, date and location of course presentation, course title, and licensee's name; and

- (i) Copy of written course materials or course outline; or
- (ii) Copy of summary of on-site commentary at multi-media courses.

5. Published articles [subparagraph (1) (c)] – Copies of published articles.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-119.

Rule 1200-6-1-.22 Qualifications, Responsibilities and Duties of Testing Personnel, is amended by deleting subparagraphs (1) (a) and (1) (b) in their entirety and substituting instead the following language, so that as amended, the new subparagraphs (1) (a) and (1) (b) shall read:

(1) (a) To become licensed as a medical laboratory technologist an applicant must:

1. Submit satisfactory evidence of successfully completing and passing a national certifying examination and being nationally certified at the technologist level by either the ASCP, NCA, NRCC, NRM, ABB, AMT or any other national certifying agency recognized by the Board (Successful completion of the Health and Human Services proficiency examination in clinical laboratory science does not meet this criteria for licensure); and
2. In addition to possessing the national certification required by part 1. of this subparagraph, submit satisfactory evidence of having met one (1) of the following educational criteria:
  - (i) A baccalaureate degree in medical technology or in one of the biological, chemical or physical sciences, and completion of a medical laboratory technologist training program that was, at the time of graduation, either
    - (I) approved or under the auspice of the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS); or
    - (II) approved by a national accrediting agency acceptable to the Board; or
    - (III) completed in a specialty program conducted by a hospital or other institution approved pursuant to Rule 1200-6-2-.04; or
  - (ii) A baccalaureate degree from an accredited college/university, completion of an accredited MLT/CLT training program and three (3) years of full time clinical laboratory work experience as defined in subparagraph (1) (h); the individual must have

completed science coursework equivalent to that required in a laboratory science education program as defined by subparagraph (1) (g); or

- (iii) A baccalaureate degree from an accredited college/university, completion of an official military laboratory procedures course of at least fifty (50) weeks duration in residence and have held the military enlisted occupational specialty of Medical Laboratory Specialist, and three (3) years of full time clinical laboratory work experience as defined in subparagraph (1) (h); the individual must have completed science coursework equivalent to that required in a laboratory science education program as defined by subparagraph (1) (g); or
- (iv) A baccalaureate degree from an accredited college/university and five (5) years of full time clinical laboratory work experience as defined in subparagraph (1) (h); the individual must have completed science coursework equivalent to that required in a laboratory science education program as defined by subparagraph (1) (g); or
- (v) For those individuals who were certified or eligible for national certification by examination at the technologists level prior to September 1, 1997 (the date on which CLIA required a baccalaureate degree for certification at the technologist level) the applicant, in addition to complying with part 1. of this subparagraph must submit satisfactory evidence of one (1) of the following:
  - (I) Having received a passing grade on a Health and Human Services proficiency examination in clinical laboratory science and having completed of five (5) years of full time clinical laboratory work experience as defined in subparagraph (1) (h); or
  - (II) Having completed both of the following:
    - I. A minimum of ninety (90) semester hours of science coursework equivalent to that required in a laboratory science education program as defined by subparagraph (1) (g) of this rule; and
    - II. A medical laboratory technologist training program that was approved at the time of graduation by the National Accrediting Agency for Clinical

Laboratory Sciences (NAACLS) or a national accrediting agency acceptable to the Board.

(1) (b) To become licensed as a medical laboratory technician an applicant must:

1. Submit satisfactory evidence of successfully completing and passing a national certifying examination and being nationally certified at the technician level; and
2. In addition to possessing the national certification required by part 1. of this subparagraph, submit satisfactory evidence of one (1) of the following educational criteria:
  - (i) Having received an associate degree from an accredited college/university and having completed an accredited medical laboratory technician training program that was approved at the time of graduation by the National Accrediting Agency for Clinical Laboratory Sciences (NAACLS) or a national accrediting agency acceptable to the Board; or
  - (ii) Having received an associate degree from an accredited college/university and having completed an official military laboratory procedures course of at least fifty (50) weeks duration in residence and having held the military enlisted occupational specialty of Medical Laboratory Specialist; or
  - (iii) Having received an associate degree from an accredited college/university which included at least six (6) semester hours of chemistry and six (6) semester hours of biology and three (3) years of full time clinical laboratory work experience as defined in subparagraph (1) (h).

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-103, 68-29-105, and 68-29-118.

Rule 1200-6-3-.02 Licensing Procedures, is amended by deleting paragraph (3) in its entirety and renumbering the remaining paragraph accordingly.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-113.

Rule 1200-6-3-.19 Preparatory Portions of Laboratory Tests, is amended by adding the following language as new subparagraph (2) (g):

(2) (g) Any activities required prior to microscopic evaluation of cytology specimens.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, and 68-29-129.

## New Rule

### Table of Contents

#### 1200-6-3-.21 Renewal of Laboratory License

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- (1) The license to operate a laboratory or collection station shall expire annually on the anniversary of the date that the license was originally issued. To continue operations, laboratories and collection stations must renew their licenses on or before the expiration date.
- (2) Methods of Renewal
  1. Internet Renewals - Laboratories and collection stations may apply for renewal and pay the necessary fees via the Internet. The application to renew can be accessed at:  
  
[www.tennessee.gov/health](http://www.tennessee.gov/health)
  2. Paper Renewals - For laboratories or collection stations that have not renewed their license online via the Internet, a renewal application form will be mailed to each laboratory and collection station licensed by the Board at least sixty (60) days prior to the expiration date to the last address provided to the Board. Failure to receive such notification does not relieve the laboratory or collection station from the responsibility of meeting all requirements for renewal.
- (3) To be eligible for renewal, a laboratory or collection station must submit to the Division of Health Related Boards on or before the expiration date all of the following:
  1. A completed renewal application form, signed by the owner and director of the medical laboratory or public official responsible for the operation of a city or county medical laboratory or institution that contains a medical laboratory; and
  2. In alphabetical order, a roster of all personnel currently employed in the laboratory, the classification/category in which the employee functions and is licensed, license number, expiration date and social security number. This shall include all medical laboratory directors, consultants, supervisors and testing personnel; and

3. The renewal and state regulatory fees as provided in Rule 1200-6-3-.02
- (4) All laboratories performing tests must file a separate renewal application for each laboratory address.
- (5) Laboratories within a hospital that are located in contiguous buildings on the same campus and under common direction may file a single renewal application or multiple renewal applications for the laboratory sites within the same physical location or street address.
- (6) Laboratories and collection stations which submit a signed renewal form or letter that is found to be untrue may be subject to disciplinary action as provided in Rule 1200-6-1-.15.
- (7) Laboratories and collection stations which fail to comply with the renewal rules or notification received by them concerning failure to timely renew shall have their licenses processed pursuant to rule 1200-10-1-.10.

Authority: T.C.A. §§ 4-5-202, 4-5-204, 68-29-105, 68-29-113, and 68-29-126.

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Contact who can answer questions concerning this notice of rulemaking hearing, technical contact for disk acquisition, and person who will approve final copy for publication: Jerry Kosten, Regulations Manager, Division of Health Related Boards, First Floor, Cordell Hull Building, 425 Fifth Avenue North, Nashville, TN 37247-1010 615-532-4397.

I certify that this is an accurate and complete representation of the intent and scope of rulemaking proposed by the Tennessee Medical Laboratory Board.

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Robbie H. Bell, Director  
Health Related Boards

Subscribed and sworn to before me this the 13th day of April, 2006.

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Notary Public

My commission expires on the \_\_\_\_\_ day of \_\_\_\_\_, \_\_\_\_\_.

The notice of rulemaking set out herein was properly filed in the Department of State on the \_\_\_\_ day of \_\_\_\_\_, 2006.

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Riley C. Darnell  
Secretary of State

By: \_\_\_\_\_